



CERTIFICATE OF GDP COMPLIANCE

We certify herewith

that the company **Chemische Fabrik Schärer & Schläpfer AG, Juraweg 45, 4852 Rothrist**, Authorisation No. 512994-102703800 with its site **Chemische Fabrik Schärer & Schläpfer AG, Juraweg 45, 4852 Rothrist, Switzerland**, Site No. 1001099 has been duly authorised to distribute medicinal products resp. API / intermediates according to the table below;

that the company is keeping the required level for Good Distribution Practices for Medicinal Products (GDP) according to the Swiss regulations in force. These regulations are in accordance with the requirements of the following documents:

- Guidelines of the European Commission on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01)
- Commission Implementing Regulation (EU) 2021/1248 on Good Distribution Practice for Veterinary Medicinal Products
- Guidelines of the European Commission on Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01)
- Commission Implementing Regulation (EU) 2021/1280 on Good Distribution Practice for active substances for veterinary medicinal products

that the company is subject to official periodic inspections; the last regular inspection has been performed on **29.06.2023** (dd.mm.yyyy).

No.	Operation	Scope*
S.4	WHOLESALE DISTRIBUTION OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	H/V
S.4.1	Wholesale distribution of non- ready-to-use medicinal products	
S.4.1.4	Active substances	
	The authorised wholesale operations do not include the storage of medicinal products	
S.5	EXPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	H/V
S.5.1	Export of non- ready-to-use medicinal products	
S.5.1.4	Active substances	
	The authorised exportation operations do not include the storage of medicinal products	

* Scope of authorisation:

- H/V Human and veterinary medicinal products, without investigational products
- V Veterinary medicinal products only, without investigational products
- I Human investigational medicinal products
- Not specified

Berne, 17.10.2023 (dd.mm.yyyy)
No. GDP-CH-1004996

Swissmedic, Swiss Agency for
Therapeutic Products



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SWISSmedic